K082235

510(K) SUMMARY

SEP - 4 2008

Name of Firm:	Blackstone Medical, Inc. 1211 Hamburg Turnpike Wayne, NJ 07470
Registration Number:	3004606875
510(k) Contact:	Whitney Törning, Senior Director of Regulatory Affairs and Quality Assurance
Telephone Number:	973.406.2838
Fax Number:	973.406.2938
Email:	wtorning@blackstonemedical.com
Submitter:	Martin G. Sprunck Regulatory Affairs Manager
Common Names:	Intervertebral Body Fusion Device Spinal Partial Vertebral Body Replacement Device
Trade Name:	PILLAR XL PEEK Spacer
System Name:	PILLAR Spacer System
Classification:	Class II
Product Codes:	MAX – Intervertebral Fusion Device with Bone Graft, Lumbar MQP – Spinal Vertebral Body Replacement Device
Regulatory Classification(s):	888.3080 - Intervertebral Body Fusion Device 888.3060 - Spinal Intervertebral Body Fixation Orthosis
Review Panel:	Orthopedic Device Panel
510(k) Date:	August 6, 2008

Substantially Equivalent Devices:

- Blackstone Medical, Inc. PILLAR Spacer System (K081177 SE 7-23-08)
- NuVasive CoRoent System (K071795 SE 12-4-07)

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Device Description:

The PILLAR™ XL PEEK Spacers consist of a variety of implants manufactured from PEEK-OPTIMA® LT (Polyetheretherketone), as described by ASTM F-2026, with Tantalum markers as described by ASTM F-560. The implants are available in a variety of footprint sizes. Additionally, they are offered in parallel and lordotic profiles in order to restore the natural curvature of the spine. The implants are available in various heights, in one millimeter increments. The superior and inferior surfaces of the implant have a pattern of ripples to provide increased stability and help prevent anterior/posterior movement of the device.

The PILLAR XL PEEK Spacers are intended for intervertebral body fusion or partial vertebral body replacement to aid in the surgical correction and stabilization of the spine.

The PILLAR XL PEEK Spacer components are not intended to be used as stand-alone devices. The PILLAR XL PEEK Spacers must be used with supplemental internal fixation and are provided non-sterile.

Intended Use / Indications for Use:

When used as an intervertebral body fusion device, the PILLAR™ Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s).

The PILLAR™ Spacer System is intended for use with autograft and supplemental internal fixation. As an example, the supplemental internal fixation system that may be used is the Blackstone Medical, Inc. Spinal Fixation System (SFS).

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PILLAR™ Spacer System.

The PILLAR™ PL spacer is used singly or in pairs, and is implanted using a posterior approach.
The PILLAR™ TL spacer is used singly or in pairs, and is implanted using a transforaminal approach.
The PILLAR™ AL spacer is used singly, and is implanted using an anterior approach.
The PILLAR™ XL spacer is used singly, and is implanted using a lateral approach.

When used as a Partial Vertebral Body Replacement (VBR) System, the PILLAR™ Spacer System is indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural

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tissues, and to restore the height of a collapsed vertebral body. The PILLAR™ Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

The PILLAR™ Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time. The Partial VBR device is intended to be used with autograft or allograft.

The PILLAR™ Spacer System is intended for use with internal fixation. As an example, the supplemental internal fixation system that may be used is the Blackstone Medical, Inc. Spinal Fixation System (SFS).

Basis of Substantial Equivalence:

Based on mechanical performance evaluations, and equivalence in configuration, indications for use, and fundamental scientific technology, the Blackstone PILLAR XL PEEK Spacers are substantially equivalent to the following devices, which have been cleared by FDA for the purpose of building a spinal implant construct in the non-cervical spine:

- Blackstone Medical, Inc. PILLAR Spacer System (K080628 SE 7-23-08)
- NuVasive CoRoent System (K071795 SE 12-4-07)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Blackstone Medical, Inc.
% Ms. Whitney G. Torning
1211 Hamburg Turnpike, Suite 300
Wayne, New Jersey 07470

SEP - 4 2008

Re: K082235
Trade/Device Name: PILLAR™ XL PEEK Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervetebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: August 06, 2008
Received: August 07, 2008

Dear Ms. Torning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K082235

Device Name: PILLAR™ XL PEEK Spacers

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Prescription Use __X__ (Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use____ (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brieh M.D.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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